

FEB 13 2002

K013312



SpineVision™

Spine systems for specialists

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: SpineVision, Inc.
3003 Summit Blvd.
Suite 1500
Atlanta, GA 30319
Phone: 404-460-5077

510(K) CONTACT: Lynnette Whitaker
Vice President, Regulatory Affairs
219-269-3701

TRADE NAME: PLUS™ Pivot Link Universal System

COMMON NAME: Rod, Hook and Screw Spinal Instrumentation

CLASSIFICATION: 888.3050 Spinal interlaminar fixation orthosis
888.3070 Pedicle Screw Spinal System

DEVICE PRODUCT CODE: Product code: 87 KWP, MNH, MNI

**SUBSTANTIALLY
EQUIVALENT DEVICES:** SCS Claris Spinal System, Orthotec, Inc.
CD Horizon, Sofamor Danek

DEVICE DESCRIPTION:

The PLUS Pivot Link Universal System spinal instrumentation consists of hooks, screws, rods and connectors that can be assembled in a variety of constructs. The instrumentation is combined and placed to treat a variety of spinal disorders, with the constructs varying according to the nature of the spinal pathology. The PLUS System components are available in stainless steel, manufactured according to ASTMs F138 and F1586.

INDICATIONS FOR USE:

When used as a posterior, non-pedicle system of the noncervical spine, the PLUS™ Pivot Link Universal System is indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e. scoliosis, kyphosis, lordosis)
- tumors
- failed previous fusion (pseudoarthrosis)

The PLUS Pivot Link Universal System is also a pedicle screw system indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the PLUS Pivot Link Universal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudoarthrosis)

BASIS OF SUBSTANTIAL EQUIVALENCE:

The components of the PLUS Pivot Link Universal System are similar in design, material, and indications to other spinal instrumentation systems that have been cleared by FDA for posterior spinal use. Mechanical testing was performed to demonstrate the equivalence of the construct design to currently marketed spinal systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynnette Whitaker
Vice President, Regulatory Affairs
SpineVision, Inc.
3003 Summit Boulevard, Suite 1500
Atlanta, Georgia 30319

FEB 13 2002

Re: K013312

Trade/Device Name: PLUSTM Pivot Link Universal System

Regulation Numbers: 888.3050 and 888.3070

Regulation Names: Spinal Interlaminar Fixation Orthosis; Pedicle Screw Spinal System;
and Spondylolisthesis Spinal Fixation Device System

Regulatory Class: II

Product Codes: KWP; MNI; and MNH

Dated: January 17, 2002

Received: January 18, 2002

Dear Ms. Whitaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for Miriam C. Probst
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013312

Device Name: PLUS™ Pivot Link Universal System

Indications for Use:

When used as a posterior, non-pedicle system of the noncervical spine, the PLUS™ Pivot Link Universal System is indicated for:

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Concurrence of CDRH, Office of Device Evaluation

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K

Prescription Use X

OR
(Per 21 CFR 801.109)

Over-The Counter Use _____